

**REMARKS**

***Status of Claims***

Claims 1-34, 43-45, 51, and 55 stand rejected as allegedly obvious under 35 U.S.C. § 103(a) by U.S. Patent No. 6,251,407 to Ganne ("Ganne") in view of the Barnett et al. article reproduced in Vaccine, Vol. 16, No. 7, pp. 746-754 (1998) ("Barnett article" or "Barnett") and U.S. Patent No. 3,269,905 to Damaskus ("Damaskus").

***Reply to Claim Rejections Under 35 U.S.C. § 103(a)***

35 U.S.C. § 103(a) states:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-34, 43-45, 51, and 55 stand rejected as allegedly obvious under 35 U.S.C. § 103(a) by U.S. Patent No. 6,251,407 to Ganne ("Ganne") in view of the Barnett article, and U.S. Patent No. 3,269,905 to Damaskus ("Damaskus"). The Examiner misapprehends the present claims, the cited references and Applicants' previous arguments. Applicants respectfully traverse this rejection.

A rejection under 35 U.S.C. § 103(a) must be supported by a clearly articulated reason why the claimed invention would have been obvious. MPEP § 2142 (Rev. 6, Sept. 2007) (citing *KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_, \_\_\_, 82 USPQ2d 1385, 1396 (2007)). The MPEP sets forth several exemplary rationales in view of the Supreme Courts decision in *KSR*. Although the Examiner does not state a specific rationale, it appears that the Examiner is basing the rejection in "Rational (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to . . . combine prior art reference teachings to arrive at the claimed invention." MPEP § 2143. As stated in MPEP § 2143, for a rejection under the foregoing rationale,

three basic criteria must be met to establish a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991).

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. MPEP § 2143.01 (citing *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347 (Fed. Cir. 1992)). The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680 (Fed. Cir. 1990).

As noted in the Response dated November 21, 2007 to the Office Action mailed May 31, 2007, which is incorporated herein by reference, Ganne discloses an emulsion (see col., 3, ll. 45-54), or compositions created by "simple mixing" (see col. 10, ll. 3-6). Ganne does not disclose storage for the composition created, except to state that the composition "must be stable preferably for at least 12 months when it is stored at 4°C." Ganne, col. 3, ll. 59-61. Separation of the antegenic medium and the adjuvant into phases in a solid state is not disclosed or suggested in Ganne. As Ganne does not disclose or suggest freezing compositions at all, it necessarily cannot disclose or suggest separate phases in a solid state. Ganne does not disclose or suggest any desirability to freeze the composition; indeed it does not discuss freezing the composition at all, and

certainly does not disclose or suggest the desirability of separating the antigenic medium and the adjuvant into separate phases in a solid state.

The secondary references fail to remedy the deficiencies of Ganne. Damaskus discloses a method for producing dry stratiform products. *See* Damaskus, col. 1, ll. 14-17. "This stratiform product can be prepared by forming a plurality of layers of separately frozen matter in stacked relation. The frozen strata can be dehydrated to obtain the multi-layer composition in dry form." Damaskus, col. 2, ll. 16-19. "The lyophilized product obtained in this process can be reconstituted with a liquid vehicle to produce a composition suitable for medical purposes." Damaskus, col. 3, ll. 28-31. Damaskus thus appears to disclose a method for producing dry stratified products. Freezing strata appears to be required only to stack the strata in order to lyophilize the layers and create a dry stratified product.

The Barnett article discloses an examination of "[t]he protective ability of two novel oil-based FMD vaccines in pigs." Barnett, abstract. The compound(s) used in Barnett are markedly distinct from the compounds disclosed in the present application. The Examiner relies on Barnett for the proposition that "concentrated stocks of vital antigen are stable for years when frozen. . . ." Office Action, page 2. Barnett discloses that, to create an "emergency ring-vaccination," "many FMD-free states have access to FMD vaccine banks, which primarily store concentrated, inactivated FMDV antigens at ultralow temperatures." Barnett, p. 746, col. 2. The antigens may be used to create vaccines; the vaccines themselves are not stored in the FMD vaccine bank. Barnett does not disclose or suggest the desirability to freeze a solid state composition, where the "one or more phases [] are distinct from each other." Barnett only discloses that frozen antigen may be stockpiled to later use to make vaccine.

In contrast, independent claims 1 and 55 disclose a "solid state" composition, where the "one or more phases [] are distinct from each other." Neither Ganne,

Damaskus, nor Barnett, alone or in combination, discloses a frozen, solid state composition, where the "one or more phases [] are distinct from each other." Ganne does not suggest that it is desirable to freeze the composition, Damaskus does not fairly suggest a frozen combination of strata over a dry combination of strata, and Barnett discloses only freezing an antigen, to later thaw and make vaccine. There is no suggestion, explicitly or implicitly of the desirability of having separate solid antigenic medium and adjuvant phases in a single composition wherein the composition would be in a liquid state at temperature greater than or equal to 4°C, as recited in the present claims. As none of the cited references, alone or in combination, suggest the desirability of their combination, explicitly or implicitly, there is no motivation to combine the references. The combination of references is improper and should be withdrawn.

Moreover, even when combined, the teachings of the cited references are deficient. The combination of the teachings would not result in the claimed multi-phase composition wherein at least one antigenic medium and the at least one adjuvant each comprise one or more phases which are distinct from each other and wherein the composition would be in the liquid state at a temperature is greater than or equal to 4°C, as recited in the claims. Although the tendency to resort to "hindsight" in examining an application is often difficult to avoid, impermissible hindsight must be avoided and the legal conclusion must be based on facts gleaned from the prior art. MPEP § 2142. Applicant respectfully submits that independent claims 1 and 55 are therefore allowable.

Claims 2-34, 43-45, and 51 depend from independent claim 1, and Applicants submit that they are themselves allowable at least because of their dependence from allowable independent claim 1. Applicant therefore respectfully requests that the rejection of claims 1-34, 43-45, 51, and 55 under 35 U.S.C. § 103(a) be withdrawn.

CONCLUSION

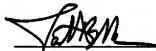
An indication of allowance of all claims is respectfully solicited. Early notification of a favorable consideration is respectfully requested. In the event any issues remain, Applicants would appreciate the courtesy of a telephone call to their counsel to resolve such issues and place all claims in condition for allowance. It is believed no fee is due. However, the Commissioner is hereby authorized to charge fees under 37 C.F.R. §§ 1.16 and 1.17 which may be required now or hereafter, or credit any overpayment, to Deposit Account No. 50-0206.

Respectfully submitted,

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